IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC.,	:	
	:	
Plaintiff,	:	
	:	Civil Action No. 1:05-CV-1416
v.	:	(Judge Sylvia H. Rambo)
	:	
MERCK & CO., INC.,	:	JURY TRIAL DEMANDED
	:	
Defendant.	:	**FILED ELECTRONICALLY**
	:	

MYLAN PHARMACEUTICALS INC.'S MEMORANDUM OF LAW IN OPPOSITION TO MERCK'S MOTION TO DISMISS

Dated: October 4, 2005

Respectfully submitted,

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Plaintiff Mylan Pharmaceuticals Inc. respectfully submits this memorandum of law in opposition to Defendant Merck & Co., Inc.'s motion to dismiss Mylan's Complaint for lack of subject matter jurisdiction.

INTRODUCTION

This action arises out of Mylan's abbreviated new drug application ("ANDA") seeking Food and Drug Administration ("FDA") approval to market a generic version of Merck's drug Proscar® (finasteride). To protect its monopoly, Merck listed U.S. Patent Nos. 5,886,184 ("the '184 patent"), 6,046,183 ("the '183 patent") and 5,942,519 ("the '519 patent") (collectively, "the patents-in-suit") in FDA's so-called "Orange Book." In doing so, Merck affirmatively declared that "a claim of patent infringement could reasonably be asserted" against any company attempting to market a generic finasteride product before these patents expire.

Mylan's ANDA certifies that its generic finasteride product would not infringe the patents-in-suit, and seeks FDA approval to begin marketing before the patents expire. Mylan's ANDA filing constitutes an act of infringement sufficient to create subject matter jurisdiction for this Court to resolve any dispute regarding infringement or validity of these patents. 35 U.S.C. § 271(e)(2)(A). While Merck has not yet sued Mylan for infringement, Merck certainly can—and Mylan has a reasonable apprehension that Merck will—bring suit in the near future. As Merck

candidly admits, FDA can approve a generic finasteride product in less than nine months.

Mylan's apprehension is objectively reasonable. For example, Merck already has asserted two of its finasteride patents against one of Mylan's competitors, Dr. Reddy's Laboratories ("Dr. Reddy's"). Merck also publicly proclaimed that it will continue to defend its finasteride patents against companies seeking to market generic products. And, of course, Merck steadfastly has refused to give Mylan a covenant not to sue or stipulation that Mylan's generic finasteride product does not infringe the patents-in-suit. In fact, Mylan already has offered to resolve this litigation on that very basis, but Merck has not responded.

Merck's motion to dismiss does nothing to assuage Mylan's legitimate fears. Merck merely states that "it had no intention of suing *within the [45-day] statutory period* during which suit would have prevented Mylan from securing approval to market its product." (Merck Mem. at 2, 10; Morry Decl. ¶ 8, Ex. A) (emphasis added). But whether or not Merck brought suit within the 45-day Hatch-Waxman period is irrelevant to this Court's analysis. Indeed, if that fact has any relevance, it hurts—not helps—Merck in light of its practice of initiating patent infringement litigation against ANDA applicants, like Mylan, *outside* this 45-day period. For instance, Merck's finasteride suit against Dr. Reddy's came nearly two years *after* the 45-day notice period expired. Thus, simply because Merck, for strategic

reasons, decided to defer commencing an infringement suit does not extinguish Mylan's apprehension. Viewing the totality of circumstances, as this Court must, Mylan has a reasonable apprehension of suit.

Although Mylan satisfies the Federal Circuit's "reasonable apprehension" test, it does not have to under Article III of the Constitution, which requires only an actual controversy between the parties. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), expressly authorizes declaratory judgment actions by generic drug companies in the circumstances presented here, so long as Article III's "actual controversy" standard is satisfied.

Because Mylan's claim for declaratory relief satisfies any standard that the Court may apply, Merck's motion must be denied. Further, this Court should reject Merck's invitation to decline jurisdiction over this action. Contrary to Merck's argument, granting Merck's motion, not denying it, would undermine Congress' express intent when enacting both Hatch-Waxman and the MMA. The only way for this Court to carry out Congress' express intent is to exercise jurisdiction over Mylan's declaratory judgment action.

For these reasons, Merck's motion to dismiss must be denied.

STATUTORY FRAMEWORK

Under Hatch-Waxman, early resolution of patent disputes is key to—and indeed necessary for—approval of generic drugs

Congress enacted Hatch-Waxman "to get generic drugs into the hands of patients at reasonable prices--fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To achieve that goal, Hatch-Waxman contains a special procedure for resolving patent disputes *before* the generic drug is marketed. First, a brand-name company—like Merck—submits information to FDA on any patent for "*which a claim of patent infringement could reasonably be asserted if* [an ANDA-filer] *engaged in the manufacture, use, or sale of the drug*." 21 U.S.C. § 355(b)(1) (emphasis added). FDA publishes this information in the "Orange Book." *Id.*

Second, an ANDA-filer must substantively address each listed patent. 21 U.S.C. § 355(j)(2)(A). Where, as here, the applicant seeks to market the generic drug before expiration of the listed patent, it must submit a so-called "paragraph IV certification" that such patent is invalid and/or will not be infringed by the generic drug, 21 U.S.C. § 355(j)(2)(A)(vii), and notify the patentee of the basis for this certification, *id.* § 355(j)(2)(B). Filing a paragraph IV application constitutes an act of infringement sufficient to vest the courts with jurisdiction to resolve the patent dispute. 35 U.S.C. § 271(e); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (explaining that 35 U.S.C. § 271(e) "define[s] act of

infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve *any* dispute concerning infringement and validity").

As an incentive for challenging patents, the first company to file a paragraph IV ANDA can receive a 180-day period of generic marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv)[1]; *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 33 (D.D.C. 2000). This exclusivity is "triggered" by the earlier of two events: (1) the first commercial marketing by the company entitled to exclusivity ("the first-filer"); or (2) a court decision of non-infringement or invalidity by *any* filer in *any* action. 21 U.S.C. § 355(j)(5)(B)(iv). Congress intended for a court decision in *any* litigation to trigger the 180-day exclusivity, even if the first-filer cannot launch its generic product, because Congress did not design this limited exclusivity incentive to block all generic competition indefinitely. *See Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 786 (Fed. Cir. 2002) ("*3M*") (Gajarsa, J. concurring).

Brand companies manipulate Hatch-Waxman to delay generic competition

Because Congress wanted patent disputes to be resolved at the same time that FDA conducted its review of the generic drug product, Hatch-Waxman encourages patentees to bring such actions within 45 days of receiving notice of the ANDA filing. Specifically, if the patentee files during this window, FDA

[1] Citations to 21 U.S.C. § 355(j)(5)(B)(iv) refer to Hatch-Waxman as it existed prior to the MMA.

automatically stays ANDA approval for up to 30 months, or until a court decision of non-infringement or invalidity, whichever is earlier. 21 U.S.C. § 355(j)(5)(B)(iii). Congress also gave the patentee the opportunity to pick the forum of its choice by preventing the ANDA-filer from bringing a declaratory judgment action during that 45-day period. 21 U.S.C. § 355(j)(5)(C).

While Congress intended patent disputes to be resolved early (during FDA's review period), brand companies nevertheless found ways to manipulate the system in order to delay generic competition and market entry, thus frustrating Congress' goal under Hatch-Waxman. One tactic—the tactic at issue here—involves delaying generic market entry by delaying the on-set of litigation. While perhaps seeming counterintuitive, brand companies have found that delaying suit can, and does, delay generic market entry.

Specifically, a brand company can bring an infringement action outside the 45-day Hatch-Waxman period. Waiting simply means that it does not get the benefit of the automatic 30-month stay of ANDA approval. But brand companies know that a generic company that launches "at risk," *i.e.*, before obtaining a judicial decision confirming non-infringement or invalidity, could face catastrophic infringement damages. Infringement damages typically are calculated on the basis of the enormous monopoly profits that the brand earns on drugs such as Proscar® or Propecia®. The brand company's lost profits dwarf the revenues that the generic

company earns selling its less-expensive drug product. Thus, lost profit damages on lucrative drugs can financially ruin most generic companies. Consequently, few generic companies risk marketing before a final judicial resolution of its patent invalidity or non-infringement claims. Thus, by refusing to bring suit immediately, brand companies create paralyzing uncertainty that allows them to continue reaping monopoly profits while generic companies struggle to obtain the certainty that they need to launch free from fear of patent infringement liability.

Merck has employed this strategy in connection with finasteride. Dr. Reddy's filed an ANDA challenging other Merck-owned finasteride patents. As it did here, Merck did not sue Dr. Reddy's during the 45-day Hatch-Waxman window, but waited nearly two years before bringing a patent infringement suit. Thus, the only reasonable inference to be drawn from Merck's response to Mylan's notice letter is that Merck does, in fact, intend to enforce its patents against Mylan.

Significantly, Congress created a system for the early resolution of patent disputes because it did not intend for ANDA-filers to be subjected to such risks and delays. Thus, while Hatch-Waxman prohibits ANDA-filers from bringing a declaratory judgment action during the 45-day notice period, it does not preclude them from bringing such an action after that period expires. Congress, in fact, intended ANDA applicants to bring declaratory judgment actions in order to attain patent certainty, avoid potentially devastating infringement damages, and obtain

court decisions that trigger generic exclusivity, thus expediting the approval of all lower-priced generic drugs. *See 3M*, 289 F.3d at 791 (Gajarsa, J., concurring) (stating that "the logical conclusion ... is to make it clear that a declaratory judgment suit is available for ANDA filers who are not sued by the NDA patentee within the 45-day period").

The MMA amends Hatch-Waxman to curb brand company abuse of the Hatch-Waxman system

Despite Congress' intent, some ANDA-filers had difficulty getting courts to exercise jurisdiction over declaratory judgment claims filed when the brand company did not sue within the 45-day notice period. The district courts often decline jurisdiction after finding that the ANDA-filer had not satisfied the Federal Circuit's so-called "reasonable apprehension" test. Because the failure to exercise jurisdiction delayed generic competition, Congress stepped in to fix the problem.

In 2003, Congress amended Hatch-Waxman through the MMA to address these abuses and "ensure that the 180-day exclusivity period ... cannot be used as a bottleneck to prevent additional generic competition." (149 CONG. REC. S15,746 (daily ed. Nov. 24, 2003), Rakoczy Decl. Tab A.)[2] To ensure that district courts would hear these declaratory judgment cases, Congress explicitly authorized "a civil action" under 28 U.S.C. § 2201 "for a declaratory judgment that the [listed]

[2] References to "Rakoczy Decl." are to the Declaration of William A. Rakoczy, submitted concurrently herewith.

patent is invalid or will not be infringed by the drug for which the applicant seeks approval...." 21 U.S.C. § 355(j)(5)(C)(i)(II).[3] Congress also directed federal courts to exercise jurisdiction over such actions "to the extent consistent with the Constitution…." 35 U.S.C. § 271(e)(5). Congress made these changes to ensure that "courts ... find jurisdiction ... to prevent ... improper effort[s] to delay infringement litigation between generic drug manufacturers and pioneer drug companies." (H.R. CONF. REP. NO. 108-391, at 836 (2003), Rakoczy Decl. Tab B.)

COUNTER-STATEMENT OF FACTS

This case involves finasteride tablets, which Merck sells under the brand-names Proscar® and Propecia®. Merck's 2004 finasteride sales totaled nearly $500 million. (Ondos Decl. ¶ 3).[4] To protect finasteride from generic competition, Merck submitted information on the patents-in-suit to FDA for listing in the Orange Book in connection with Proscar®, thus affirmatively declaring to the world that it could reasonably assert a claim for infringement on these patents against any generic ANDA-filer, including Mylan. *See* 21 U.S.C. § 355(b)(1).

Mylan's generic competitor, Dr. Reddy's, filed an ANDA for generic finasteride/Propecia® challenging certain of Merck's finasteride patents.

[3] The changes to the declaratory judgment provision apply to all proceedings, including this one, pending on or after December 8, 2003. MMA § 1101(c)(1).

[4] References to "Ondos Decl." are to the Declaration of Jill M. Ondos, submitted concurrently herewith.

Dr. Reddy's paragraph IV ANDA constituted an act of patent infringement. As previously discussed, Merck refrained from filing suit for nearly two years. Merck's suit, filed in September 2004, remains pending.

Mylan spent years and millions of dollars developing and filing an ANDA for its own generic finasteride/Proscar® drug product. (Ondos Decl. ¶¶ 6-7). Like Dr. Reddy's, Mylan also sought to market prior to the expiration of certain of Merck's finasteride patents. And, as with Dr. Reddy's, for strategic business reasons Merck did not sue Mylan within the 45-day notice period. As Merck knew, without patent certainty, most generics will not launch at-risk. Mylan thus had no option but to invoke the statutory provisions that Congress enacted by filing this suit in order to obtain patent certainty and approval of its product.

COUNTER-STATEMENT OF QUESTIONS INVOLVED

1. Under the totality of the circumstances, including Merck's practice of delaying the on-set of litigation until after expiration of the 45-day Hatch-Waxman notice period, has Merck engaged in conduct sufficient to give Mylan a reasonable apprehension that Merck will sue for infringement of the patents-in-suit?

2. Under the plain language of the MMA and controlling Supreme Court precedent, does Mylan have to establish more than the following elements in order to prove the existence of an "actual controversy" under Article III of the

Constitution: (a) an actual or imminent injury-in-fact, (b) that is fairly traceable to Merck, and (c) is redressible by a favorable decision by this Court?

ARGUMENT

Based on the totality of the facts presented here, Mylan satisfies the two-part "reasonable apprehension" test that Merck argues controls the outcome of its motion. Despite satisfying this test, the fact remains that Mylan need only satisfy Article III's case or controversy requirement in order to establish the existence of subject matter jurisdiction. As amended by the MMA, Hatch-Waxman expressly authorizes Mylan to file this action and directs this Court to exercise jurisdiction to the maximum extent permitted by the Constitution, which extends to all cases and controversies under Article III. If such controversy exists, as it does here, subject matter jurisdiction exists regardless of the reasonable apprehension test.

I. Mylan Satisfies The Federal Circuit's "Reasonable Apprehension" Test for Subject Matter Jurisdiction.

Contrary to Merck's suggestion, the reasonable apprehension test merely requires that (1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the patentee will bring suit if the activity in question continues. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997).

Merck does not dispute that Mylan has acted or made preparations to act in a way that would constitute infringement, satisfying the first part of the test. *See id.*; 35 U.S.C. § 271(e)(2)(A).[5] Merck's motion instead argues that Mylan lacks a reasonable apprehension of suit under the second prong. Merck is wrong.

Merck's entire argument boils down to the unfounded assertion that Mylan lacks a reasonable apprehension because Merck has represented that "it had no intention of suing within the [45-day] statutory period…." (Merck Mem. at 2, 10; Morry Decl. ¶ 8). Merck's argument is fatally flawed. Mylan can have a reasonable apprehension of suit even though Merck did not sue within this 45-day period. Merck did, after all, sue Dr. Reddy's on certain finasteride patents nearly two years *after* the 45-day period expired.

Merck has said nothing to Mylan or this Court about its intentions *after* the expiration of this 45-day period. Thus, the unspoken end to Merck's statement that it "has not sued, threatened to sue, or charged Mylan with infringement" is "*yet*." (Merck Mem. at 9). And, of course, Mylan does not have to wait for a suit or

[5] *See also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Glaxo*, 110 F.3d at 1571 (holding first prong satisfied where plaintiff submitted an ANDA to FDA); *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1401 (Fed. Cir. 1995); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 826 (N.D. Ill. 2004); *Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 317-18 (S.D.N.Y. 2003); *Dr. Reddy's Labs., Ltd. v. aaiPharma Inc.*, No. 01 Civ. 10102(LAP), 2002 WL 31059289, at *9-10 (S.D.N.Y. Sept. 13, 2002), Ex. A to Appendix to this Memorandum ("App."), submitted concurrently herewith; *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008-09 (N.D. Ill. 2001).

threats from Merck before this Court may find declaratory judgment jurisdiction because "[s]uch a requirement would utterly defeat the purpose of the Declaratory Judgment Act, which in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987) (citation omitted).

In assessing whether a reasonable apprehension exists under the test's second prong, the Court must consider the "totality of the circumstances," rather than focusing on isolated events or conduct. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1998); *see also C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 880 (Fed. Cir. 1983). But Merck does just that—impermissibly ignores the totality of its conduct in favor of an improper "divide and conquer" approach, addressing each fact in isolation from the other. Merck argues, for example, that "a history of patent enforcement ... does not create a reasonable apprehension *in and of itself*." (Merck Mem. at 17) (emphasis added). Mylan does not suggest otherwise. Viewing the ***totality*** of circumstances, as this Court must, Merck is no mere "quiescent" patentee being dragged into court without reason. Under the totality of the circumstances, Mylan has a reasonable apprehension of suit, and this Court has jurisdiction.

A. Merck's Orange-Book listing of the patents-in-suit, alone, gives rise to a reasonable apprehension of suit.

By listing the patents-in-suit in the Orange Book, Merck affirmatively represented that a claim for infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale" of *any* generic finasteride drug. 21 U.S.C. § 355(b)(1). This listing alone establishes a reasonable apprehension of suit.

Judge Gajarsa of the Federal Circuit correctly explained that while Hatch-Waxman does not permit an ANDA-filer to file a declaratory judgment action during the 45-day period, it expressly provides for such an action after that period. *3M*, 289 F.3d at 790-91 (Gajarsa, J., concurring). It also is no coincidence, Judge Gajarsa explained, that Hatch-Waxman's patent-listing requirements closely track the Federal Circuit's requirements for jurisdiction:

> Thus, by the terms of the statute, filing an NDA application meets prong one of the declaratory judgment case or controversy requirement, because filing the application requires the patentee to maintain that an infringement suit could 'reasonably be asserted' against one who 'engages in the manufacture, use or sale of the drug.' This is 'conduct giving rise to a reasonable apprehension on the plaintiff's part that it will face an infringement suit or the threat of one.'

Id. at 791 (Gajarsa, J., concurring) (citation omitted).

This reasoning is compelling in the instant case. Merck is not a "quiescent patent owner" who "has done nothing but obtain a patent." Merck listed the patents-in-suit in the Orange Book, thus declaring to all prospective generic

applicants that an infringement suit could be reasonably asserted against them. Merck argues that a listing does not evince an intent to sue. (Merck Mem. at 19-20). But this misses the point. Merck does not deny, nor could it, that, had Merck sent Mylan a letter stating that it *could* sue Mylan for infringement of the patents-in-suit, *such a communication would undoubtedly give rise to a reasonable apprehension of suit* would exist. *See Glaxo*, 110 F.3d at 1569. Listing these patents is equivalent to such a communication, and thus does not insulate Merck from suit.

B. Merck's assertion of its finasteride patents against Dr. Reddy's is powerful objective evidence that a reasonable apprehension of suit exists here.

While Merck's motion ignores the fact that it has asserted two of its finasteride patents against Dr. Reddy's, this Court should not. It is well-settled that a patentee's filing of infringement litigation against other parties over a similar product supports a finding of "reasonable apprehension." *See, e.g., Arrowhead*, 846 F.2d at 737 (finding reasonable apprehension where suit against third party "evidenced not only an intent but a willingness and capacity to employ litigation in pursuit of its patent rights"); *Teva Pharms.*, 301 F. Supp. 2d at 824-26 (same); *Ivoclar Vivadent, Inc. v. Hasel,* No. 02-CV-0316E(F), 2003 WL 21730520, at *6 (W.D.N.Y. June 30, 2003) (same), App. Ex. B; *Super Prods. Corp. v. D P Way Corp.*, 546 F.2d 748, 754 (7th Cir. 1977) (finding that "although the defendant had

not accused the plaintiff of infringement, the plaintiff could reasonably expect infringement litigation because of the similarity of its own product to the defendant's patented product").

The fact that Merck waited nearly two years to sue Dr. Reddy's for infringement of its finasteride patents also seriously undermines Merck's current "imminence" argument. (Merck Mem. at 14). The fact is, the law does not require imminence, but only "an intent [on the part of the patentee] to enforce its patent...." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996) (stating that reasonable apprehension "does not require an express charge of infringement"). Indeed, the Federal Circuit repeatedly has held that a "patentee's present intentions do not control whether a case or controversy exists," and that a plaintiff need not show that the patentee "is 'poised on the courthouse steps.'" *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) (citations omitted). As the Federal Circuit has explained:

> It would obviously be unrealistic to limit the required apprehension to one of imminent suit against plaintiff when defendant is exhibiting an intent to delay that suit until after defendant's extra-judicial enforcement efforts have failed and a trial date more convenient for defendant has arrived.

Arrowhead, 846 F.2d at 736-37 (citation omitted).

Thus, the Declaratory Judgment Act cannot be read "so narrowly as to require that a party actually be confronted with an *express* threat of litigation to meet the requirements of an actual case or controversy." *Goodyear*, 824 F.2d at

956; *accord Arrowhead*, 846 F.2d at 736 (recognizing that "the courts have not required an express infringement charge"). Indeed, "[i]f the circumstances warrant, a reasonable apprehension may be found in the absence of *any* communication from defendant to plaintiff." *Arrowhead*, 846 F.2d at 736 (citation omitted). This is particularly true where, as here, the patentee (Merck) has evidenced an intent to delay suit until a more strategically advantageous time (against not only Dr. Reddy's, but now Mylan).

Even if the Court is persuaded by Merck's "imminence" argument, Merck has offered nothing to diminish the fact that Mylan suffers from an imminent apprehension of suit. Contrary to Merck's assertion, Mylan's reasonable apprehension is not "at an unforeseen time in the future." (Merck Mem. at 14). As Merck itself admits, companies may begin selling generic finasteride products as early as June 2006—in less than nine months. (*See id.* at 9, 21-22, 27).

Ignoring the significance of these facts, Merck erroneously focuses on the fact that it has not sued "first filer" Ivax. (Merck Mem. at 16; Morry Decl. ¶ 9.) But the unspoken end of that sentence is, again, "*yet*." In any event, merely because Merck has not yet filed suit against Ivax or Mylan is not dispositive of its future intentions. This is particularly true here, where Merck has engaged in a course of conduct demonstrating not only a practice of waiting to sue, but a willingness to protect its finasteride franchise. *See Goodyear*, 824 F.2d at 956. As

the Federal Circuit has held, the "law does not require enterprises to keep their heads in the sand while a patentee picks them off one by one and at its leisure." *Arrowhead*, 846 F.2d at 738.

C. Merck's public statements that it will aggressively defend its finasteride patents further evidence an objective and reasonable apprehension of suit.

Even if Merck's patent listing did not evidence an intent to sue (which it does), Merck's public statements leave no room for doubt, especially when combined with its finasteride patent suit against Dr. Reddy's. Merck has publicly stated that it "intends to vigorously defend its patents, which it believes are valid, against infringement by generic companies attempting to market products prior to the expiration dates of such patents." (Rakoczy Decl. Tab C). Such statements are an important part of the totality of circumstances. *See Dr. Reddy's*, 2002 WL 31059289, at *7. Merck dismisses this fact, suggesting that its statements are irrelevant because Merck made no "blanket statement" that "it would sue all" ANDA-filers. (Merck Mem. at 21). Again, Merck is mistaken.

"[T]he threat of suit for patent infringement does not have to be direct or specific. Implication is sufficient." *Millipore Corp. v. Univ. Patents, Inc.*, 682 F. Supp. 227, 232 (D. Del. 1987) (citations omitted). And such statements can create a reasonable apprehension even when "may be made ... to the industry at large." *Nippon Elec. Glass Co. v. Sheldon*, 489 F. Supp. 119, 121 (S.D.N.Y. 1980)

(citations omitted); *see also DuPont*, 62 F.3d at 1401 (same); *Kos Pharms.*, 242 F. Supp. 2d at 316-17 (same); *Millipore*, 682 F. Supp. at 232 (same); *Sigma-Tau Industrie Farmaceutiche Riunite, S.p.A. v. Lonza, Ltd.*, 36 F. Supp. 2d 26, 30 n.5 (D.D.C. 1999) (same). Indeed, at least one court has ruled that a patentee's statements directed to generics generally, *alone*, were sufficient to establish reasonable apprehension of suit. *Dr. Reddy's*, 2002 WL 31059289, at *7.

Merck's statements specifically concerned finasteride which, as Merck admits, is the same generic product at issue here. Thus, Merck's own public statements, particularly coming on the heels of its finasteride patent suit against Dr. Reddy's, are highly pertinent here. At the very least, they reinforce and confirm Mylan's reasonable apprehension of suit.

D. Merck's prior history of litigation to protect its patents further reinforces Mylan's reasonable apprehension of suit.

This Court also should consider Merck's litigious nature. Merck aggressively defends its intellectual property and drug monopolies from generic competition by routinely bringing suit against ANDA-filers. In addition to its current finasteride suit against Dr. Reddy's, Merck has sued numerous companies seeking to make generic versions of other Merck products. (Rakoczy Decl. Tabs C, D). Indeed, Merck has instituted over 25 lawsuits against generic companies in the last five years alone, with at least 13 of those lawsuits filed in the last two years, including a suit against Mylan involving Merck's brand-name Fosomax®.

(Rakoczy Decl. Tab D; *Merck & Co., Inc. v. Mylan Pharmaceuticals Inc.*, 03-cv-01953-GEL (S.D.N.Y.)). Other patent litigation between Merck and Mylan likewise is, of course, material to the Court's analysis. *See Goodyear Tire*, 824 F.2d at 955; *Teva Pharms.*, 301 F. Supp. 2d at 824-26; *Kos Pharms.*, 242 F. Supp. 2d at 315; *Dr. Reddy's*, 2002 WL 31059289, at *8.

In short, Merck consistently employs patent litigation to protect its branded drug monopolies—an important and relevant factor for this Court to consider in determining whether Mylan has a reasonable apprehension. *C.R. Bard*, 716 F.2d at 881 & n.6; *Clontech Labs., Inc. v. Life Techs., Inc.*, No. Civ.A. AW-00-1879, 2000 WL 33124811, at *2 (D. Md. Dec. 20, 2000) (recognizing that "'a patent owner's willingness and capacity to enforce its patent rights is pertinent to the inquiry for an actual controversy'"), App. Ex. C; *SmithKline Beecham Corp. v. Zenith Goldline Pharms., Inc.*, No. CIV.A.00-CV-1393, 2000 WL 963165, at *2 (E.D. Pa. June 28, 2000), App. Ex. D; *Medtronic, Inc. v. Am. Optical Corp.*, 327 F. Supp. 1327, 1333 (D. Minn. 1971).

E. Merck refuses to acknowledge that Mylan does not infringe the patents-in-suit, or otherwise promise not to sue Mylan.

Merck has refused to acknowledge that Mylan's product does not infringe the patents-in-suit or otherwise provide Mylan a covenant not to sue. (Ondos Decl. ¶¶ 11, 13). Contrary to Merck's assertions, this, too, is relevant to the Court's analysis. *See BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir.

1993) (finding relevant a "patentee's refusal to give assurances that it will not enforce its patents"); *Kos Pharms.*, 242 F. Supp. 2d at 317 (same); *Gen. Latex & Chem. Corp. v. BASF Corp.*, C.A. No. 99-038-SLR, 1999 U.S. Dist. LEXIS 22904, at *8 (D. Del. July 14, 1999) (same), App. Ex. E.

Merck responds only that it is not obligated to provide such reassurances, and that it otherwise has expressed that it would not sue Mylan *within* the 45-day period. (*See* Merck Mem. at 18). Maybe so, but Merck cannot have it both ways—arguing on one hand that Mylan lacks any reasonable apprehension of suit while, on the other, refusing to give Mylan the assurances that it needs to eliminate its current apprehension. Merck cannot credibly argue that Mylan lacks a reasonable apprehension where Merck has provided Mylan a cryptic, two-line letter merely stating that "it is not [Merck's] intention to bring suit ... *within* the 45 day period" (Morry Decl. Ex. A), but has refused to disavow any intent to file suit *after* expiration of the 45-day period. Thus, Merck's claim that it has "stepped aside and forfeited its right to prevent the FDA from approving Mylan's ANDA" is not only disingenuous, but irrelevant. (Merck Mem. at 10). Just as Merck sued Dr. Reddy's after the 45-day notice period, Mylan too maintains a reasonable apprehension that Merck intends to sue Mylan for infringement of the patents-in-suit after this period.

In the end, if Merck truly believes that Mylan has nothing to fear, then Merck can provide Mylan with a stipulation of non-infringement and covenant not to sue in order to resolve this matter. That Merck refuses to do so speaks volumes about its intentions to sue Mylan or, at the very least, hold its patents over Mylan like a modern-day sword of Damocles—which is precisely what Congress designed the Declaratory Judgment Act to remedy.

II. Mylan's Claim For Declaratory Relief Presents A Justiciable Case Or Controversy Under Article III Of The Constitution.

While it satisfies the two-prong reasonable apprehension test, Mylan does not have to for this Court to have subject matter jurisdiction. Mylan need only satisfy the Article III case or controversy standard for jurisdiction to exist. Indeed, as even the majority in *Teva* concedes, the "traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1335 (Fed. Cir. 2005). Thus, an actual controversy under Article III can, and does, exist outside or regardless of any reasonable apprehension of suit.

A. The MMA bestows subject matter jurisdiction so long as a "case or controversy" exists.

Under the MMA, Congress specifically authorized ANDA-filers to bring declaratory judgment actions on Orange-Book listed patents, such as the one Mylan has brought here. *See* MMA § 1101(a)(2)(C) (codified at 21 U.S.C.

§ 355(j)(5)(C)). Congress also instructed that federal courts "shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any such action." 35 U.S.C. § 271(e)(5). Congress enacted the MMA's declaratory judgment provision to ensure that "courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." (H.R. CONF. REP. NO. 108-391, at 836, Rakoczy Decl. Tab B; *see also* 149 CONG. REC. S15,746 (stating that district court "must hear these declaratory judgment cases to the maximum extent permitted by the Constitution"), Rakoczy Decl. Tab A).

Relying on the *Teva* decision, Merck argues that the MMA changed nothing and that an ANDA-filer can bring a declaratory judgment action now only if it could have before the MMA by satisfying the reasonable apprehension test. (*See* Merck Mem. at 23-25). This argument flies in the face of Supreme Court precedent holding that "[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." *Stone v. INS*, 514 U.S. 386, 397 (1995) (citations omitted). Had Congress intended for declaratory judgment actions to proceed no differently now than before the MMA, as Merck argues, there would have been no reason for Congress to include the new declaratory judgment provisions in the MMA. But it did so, and this Court must give those provisions "real and substantial effect." *Stone*, 514 U.S. at 387. The

only way to do that here is to exercise jurisdiction to the maximum extent allowable under the Constitution, which plainly is limited only by Article III.

B. Mylan's suit presents a controversy cognizable under Article III of the Constitution.

According to the Supreme Court, the only prerequisite to jurisdiction under the Declaratory Judgment Act is an "actual controversy" under Article III, which merely requires: (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 239-40 (1937); *Bennett v. Spear*, 520 U.S. 154, 167 (1997). The facts of this case easily satisfy Article III.

Mylan seeks to market a generic finasteride product, in connection with which Merck listed the patents-in-suit in the Orange Book and declared that "a claim of patent infringement could reasonably be asserted" against any unlicensed generic ANDA-filer. 21 U.S.C. § 355(b)(1). Merck's enforcement of those patents could prevent Mylan from selling its generic product, nullifying Mylan's significant investments in research and development and potentially subjecting any profits to the uncertainty of a future lawsuit. Merck's assertion of two of its finasteride patents against Dr. Reddy's only amplifies these facts. Were Merck to bring an action against Mylan for infringement of the patents-in-suit, no one disputes that such a case would squarely fall within Article III's "arising-under" jurisdiction. Thus, Merck is wrong even to suggest that "[t]his is not a controversy

between Mylan and Merck." (Merck Mem. at 22). Unless Merck acknowledges that Mylan's product does not infringe and provides a covenant not to sue (which it refuses to do), an actual controversy exits between Merck and Mylan.

Additionally, Merck and Mylan have clear and adverse legal interests regarding infringement of the patents-in-suit. Mylan has invested considerable resources preparing and filing its ANDA—an investment that could be lost if Merck mounts a successful infringement action. (Ondos Decl. ¶ 7). These losses would be even more substantial if a court rules that Mylan's product infringes the patents-in-suit *after* Mylan begins marketing that product. Thus, Mylan suffers a real, significant, and defined harm where uncertainty exists regarding its right to manufacture and sell generic finasteride. *See Northeastern Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville, Florida*, 508 U.S. 656, 664-68 (1993) (finding injury under Article III where plaintiff was precluded by law from competing).

Moreover, Merck is directly responsible for Mylan's injury. Merck obtained the '184, '183, and '519 patents; declared that those patents would be infringed by anyone attempting to market the product that Mylan seeks to market before patent expiration; stated publicly that it will defend its finasteride patents; asserted its finasteride patents against Mylan's generic competitor; and refused to provide

Mylan with any assurance that Mylan's generic finasteride product does not infringe those patents or otherwise promise not to sue Mylan.

Finally, resolving this conflict will not lead to an advisory opinion, as Merck contends. (Merck Mem. at 24-25). A declaration of non-infringement from this Court would allow Mylan to market its product without the risk of incurring massive damages for infringing a patent on a highly lucrative drug. Thus, no one legitimately can dispute that Mylan would tangibly benefit from the Court's intervention. Such intervention is, in fact, the *only* way that Mylan can obtain approval in the first instance, as well as market its generic product free from infringement liability. It is difficult to conceive of a setting in which application of the Declaratory Judgment Act would be more appropriate.

III. The Relief Mylan Seeks Comports With Congress' Express Desire To Increase Generic Market Entry.

Merck argues that this Court should, in its discretion, decline jurisdiction over this case because a decision here could impact the right of another company (Ivax) to the 180-day generic exclusivity period. (Merck Mem. at 21-22, 26). Setting aside the absurd notion that Merck, a brand company, has any legitimate interest in this generic exclusivity period, Merck is wrong on the merits of its argument. Indeed, Mylan's suit furthers—not frustrates—Congress' express intent when enacting Hatch-Waxman and the MMA.

As an initial matter, the courts uniformly agree that filing a declaratory judgment action is a perfectly acceptable means—and in some cases the only way—to obtain FDA approval, even if it means triggering another company's 180-day generic exclusivity period. *See 3M*, 289 F.3d at 780 (recognizing that a subsequent applicant can obtain a favorable court decision triggering the first-filer's exclusivity); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1009 (D.C. Cir. 1999) (same).

More importantly, bringing a declaratory judgment suit, even if done solely for the purposes of triggering generic exclusivity, is entirely consistent with Congressional intent. Congress enacted Hatch-Waxman (and subsequently the MMA) "to get generic drugs into the hands of patients at reasonable prices--fast." *Barr*, 930 F.2d at 76; *see also 3M*, 289 F.3d at 786 (Gajarsa, J., concurring) ("The Congressional policy with respect to generic drugs is clear: generic manufacturing of a drug should be allowed as soon as it is determined that it does not violate patent rights."). And, as Judge Gajarsa explained in unambiguous terms, "allowing first ANDA filers to hold up all the generic drug manufacturers for an indefinite amount of time would stifle Congress's attempt to expedite the marketing of generic products." *3M*, 289 F.3d at 786 (Gajarsa, J. concurring). It is therefore, according to Judge Gajarsa, incumbent upon an ANDA-filer to obtain a court decision through a declaratory judgment action.

Thus, Merck offers this Court no valid policy reasons for declining to hear Mylan's declaratory judgment action. And, in fact, the policy behind the entire Hatch-Waxman scheme calls out for this Court to exercise jurisdiction over this dispute.

CONCLUSION

Under the facts of this case, Mylan satisfies both the reasonable apprehension and Article III tests for subject matter jurisdiction. That Merck refuses to resolve this matter by stipulating to non-infringement and promising not to sue Mylan only highlights the actual controversy between the parties. The Court therefore should deny Merck's motion to dismiss for lack of subject matter jurisdiction and resolve this case on its merits.

Dated: October 4, 2005

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH LR 7.8

This brief complies with the word limitation approved by the Court in its Order dated September 30, 2005, because it does not exceed 6,500 words. More specifically, this brief contains 6,455 words.

Dated: October 4, 2005

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CERTIFICATE OF SERVICE

I, Amy D. Brody, Esq., one of the attorneys for plaintiff, hereby certify that the foregoing **Mylan Pharmaceutical Inc.'s Memorandum of Law in Opposition to Merck's Motion to Dismiss** has been served this 4th day of October, 2005 by the Court's Electronic Case Filing (ECF) system to the following:

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